



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 19 1999

Food and Drug Administration
Washington, DC 20204

5309 '99 FEB 23 P1:49

President
Performance Labs, Inc.
5115 Douglas Fir Road, Unit 1
Calabasas, California 91302-1441

Dear Sir:

This is in response to your letters of February 9, 1999 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submissions state that Performance Labs, Inc. is making the following claims, among others, for the product:

CardioMax™

"...reduce total cholesterol," "reduce LDL "Bad" cholesterol".

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggests that it is intended to treat, prevent, or mitigate a disease, namely hypercholesterolemia. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.
Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200
FDA, Los Angeles District Office, Office of Compliance, HFR-PA240

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cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (file)

HFS-450 (r/f, file)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-605 (Bowers)

HFV-228 (Benz)

HFV-232 (Brown)

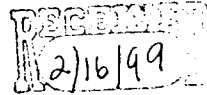
GCF-1 (Dorsey)

f/t:HFS-456:rjm:2/17/98:docname:63725.adv:disc35

PERFORMANCE LABS. INC.

February 9, 1999

Office of Special Nutritionals (HFS-450)
FDA-CFSAN
200 C Street, S.W.
Washington, DC 20204



Dear Sirs:

In accordance with the statutory provisions of 21 USC 343(r)(6), we are providing you with notice of the type of statement(s) to which that section refers.

Distributor's name and address:

Performance Labs, Inc., 5115 Douglas Fir Road, Unit I, Calabasas, CA 91302-1441.

Statements:

Cholesterol Control Program ✓Diet, ✓Exercise, ✓CardioMax

Healthy Cholesterol, Naturally.

Clinically Supported to: Reduce Triglycerides Reduce Total Cholesterol
Reduce LDL "Bad" Cholesterol Increase HDL "Good" Cholesterol

Safe, Effective Cardiovascular Health Formula

CardioMax is a dietary supplement designed to help you safely balance your cholesterol and improve your cardiovascular health—without the side effects of some prescription drugs. As part of a complete cholesterol control program, CardioMax stabilizes the metabolic imbalance at the root of elevated cholesterol through a unique blend of natural vitamins, minerals and herbs that combine the centuries-old power of Chinese naturopathy with modern scientific research.

World-Class Botanicals Provide Natural Benefits

Each tablet contains Chromium, Magnesium, Vitamin E and Taurine—micronutrients recommended by doctors. CardioMax also contains a precise blend of herbs and nutrients including:

Garlic & Hawthorn Berry Widely prescribed in Europe to strength and regulate cardiovascular function.

Cassia Seed, Alisma, Ho Shou Wu, Lotus Leaf Used for centuries in China to help moderate metabolic imbalances associated with the heart.

Dietary ingredient(s) to which the statements refer: Vitamin E, Magnesium, Chromium, Deodorized Garlic, Hawthorn Berry, Taurine, Cassia Seed, Alisma, Ho Shou Wu, Chrysanthemum, Lotus Leaf

Name of the supplement bearing the label or associated with the labeling:

Performance Labs Inc.—**CardioMax™**

Respectfully submitted,

Performance Labs, Inc.